Regardless, the undersigned affirms the election of claims 1-11, 15, and 16 for examination, even though it is not explained in Paper No. 8 why adding an additional element to the device of claim 1, as recited in claim 12, creates a patentably distinct species.

Amendments

Claims 1 and 15 have been amended to more particularly point out, as argued in the prior response, that the plain meaning of "protuberance", as that term is used in the specification, is akin to a bulge, bump, hump, or prominence; the latter also being used in the medical area (copy of *Dorland's Illustrated Medical Dictionary* (Philadelphia: W.B. Saunders Company, 1965) entry for "protuberance" attached). As amended, the claims specifically recite that the protuberance is formed from and extends from the body and without leaving an aperture in the body from which the protuberance is formed. No new matter is presented.

These amendments were not made earlier as the previous amendment changing "projection" to "protuberance" and the accompanying remarks and explanation of the amended term, with reference to the specification, was believed to have made the same point as now made with the present amendment. Accordingly, pursuant to § 1.116(c), and the following remarks, these amendments should be entered. None of the cited art shows protuberances as that term is used in the specification of this application, and even more clearly in light of the present amendments.

Rejection under 35 U.S.C. 102

The rejection of claim 1 over Tessman (*et al.*) hereunder is still traversed, especially in light of the present amendments..

As is eminently clear, the protuberances as defined by the claims as now amended are unlike the teeth-like projections in Tessman. Note Fig. 5 of

Tessman, a cross section of the body shown in Fig. 2, wherein the projections are not formed from the body, but are separate "hook-like" projections, not protuberances, and are physically separate from the silicone rubber material of the tubular portion of the body. Column 2, lines 29-43. *See also* col. 2, ln. 30-32: the "elongated tube 11" is "a metal tube covered with a medical grade silicone rubber." Accordingly, the present claims are not anticipated by this reference because the projections are not protuberances formed from the body but are separate from and embedded in the body. There is clear structural difference.

Rejection under 35 U.S.C. 103

The rejection of claims 1-4, 6, 9-10, and 15 as obvious over Schnepp-Pesch (*et al.*) in view of Tessman is still traversed, especially in light of the present amendments.

As the primary reference is cited for its having a cylindrical body and plate-like (flat) member, and the secondary reference is cited for teaching what are alleged to be "protrusions/protuberances", as noted in the rejection under 35 U.S.C. 102, the secondary reference does not show or suggest "protuberances" as that term is used in the specification and defined by the amended claims. Because the hook-like projections are separate from the body in the Tessman device, the combination of references must be based on the Schnepp-Pesch embodiment wherein the stent is embedded in plastic (col. 3, ln. 38-43) in order to provide a substrate to which Tessman's hook-like projections are attached. Otherwise, there is no teaching how the hook-like projections of Tessman would be attached to the Schnepp-Pesch device.

Therefore, claims 1 and 15, and those dependent thereon would not have been obvious from this combination of references.

The combination of Wolff (*et al.*) with Tessman is likewise deficient. The Wolff device is made of welded wires (col. 3, ln. 3-7). There is no teaching in the combination of references how Tessman's protuberances, which are embedded

in an overlying substrate, can be formed on the Wolff wires, which are only 16 mils in diameter (col. 4, ln. 50-51) for larger arteries. In fact, the Wolff device is intended to penetrate into the lumen wall to stimulate growth of tissue over the wire stent (col. 6, ln. 42-46). Accordingly, Wolff is not properly combined with Tessman, and even in combination does not render the claims obvious.

Remarks on Examiner's Response to Amendment

The Examiner's statement that "[i]t is well known in the art that a protrusion is [*sic*] also encompasses a protuberance" (¶14) is incorrect, unsupported, and contrary to law. That a single reference (Williams) uses the terms 'protrusion' and 'protuberance' interchangeably, or inexactly, does not fix the meaning of the term within the art; such usage is merely a single evidence of use. Even further:

> The written description must be examined in every case, because it is relevant not only to aid in the claim construction analysis, but also to determine if the presumption of ordinary and customary meaning is rebutted. The presumption will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth a definition of the term different from its ordinary and customary meaning.

Brookhill-Wilk 1, LLC, v. Intuitive Surgical, Inc., 02-1145, http://www.fedcir.gov/dailylog.html (Fed. Cir., 11 April 2003) (last paragraph of section B.I.) (citations omitted). The Examiner cannot ignore that the term "protuberance" as used in the specification and the claims of this application is different from the "projections" in the cited art. The Williams "projections" clearly define apertures in the body, which structure is precluded by the claims as presently amended. Neither can the description in Tessman of "hook-like" projections be equated with the claimed protuberances being formed from the body without contradicting the specific disclosure in Tessman. Accordingly, the "protuberance" of this invention is not the same as the prior art structure even if the same term is used.

Applicants stand by their previous remarks and the explicit disclosure in Tessman that the "relatively sharp teeth . . . serve as a projection to anchor the stent" (col. 2, ln. 54-56) and thereby cause more tissue damage that the instant protuberances that are not "hook-like." Note also column 2 (ln. 40-43) in Tessman, that the device can be covered with a lubricant that "prevents the projections from causing any *damage* until the [lubricant] layer is washed away." The use in Tessman of "relatively sharp teeth" and "hook-like" projections, and acknowledgment that the projections cause damage without an overlying lubricant, is contrary to the meaning of "protrusion" alleged in the rejection. The Tessman protrusions clearly penetrate the lumen tissue while the instant protuberances do not.

The remainder of ¶15 of the communication is not understood. Whether the device is rotated as an Tessman or expanded as in either reference (both use memory metals; *see* Tessman at col. 2, ln. 48, and Schnepp-Pesch in the abstract), the reference protrusions are sharp, unlike the claimed protuberances.

Also (and consistent with § 1.104(d)(2)) the Examiner is requested to explain the basis for alleging that the lumen surface "will not snag the Tessman raised surfaces" considering that Tessman defines those surfaces as "hook-like" and acknowledges that, unless lubricated, they will cause damage. The supposition by the Examiner is directly contrary to the plain teaching of the reference.

Finally, Applicants traverse the Examiner's interpretation of the art made of record and not specifically relied up; namely, that any of that art shows or suggests "protuberances" as defined in the present application or claims. In particular: Williams is discussed above as having teeth leaving apertures; Savin *et al.* shows a cage and not projections or protuberances; and Zilber has no plate but is a molded silicone stent (Fig. 3) or a fabric-coated stent (Fig. 2).

Conclusion

The claim amendments further clarify the amendments and remarks in Applicants' previous response and thus do not raise new issues or new matter. The amendments now even more particularly define the "protuberances" on the surface of the device so as to definitively distinguish the cited Tessman reference. The Tessman reference uses hooks as projections embedded within a circular stent tube. Any valid combination of Schnepp-Pesch with Tessman, in order to have protrusions, requires the Schnepp-Pesch embodiment where the stent is embedded in plastic, which forms the substrate for embedding the Tessman "hook-like" projections. Wolff only discloses the use of a wire, contrary to Tessman's tube, and there is no teaching, even in combination, how protrusions can be formed thereon. None of this art shows or suggests a stent having protuberances formed from the stent body. Therefore, the claims are not anticipated or obvious, and the present rejections should be withdrawn.

Respectfully submitted,

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APPENDIX SHOWING MARK-UPS OF AMENDMENTS

IN THE CLAIMS:

1. (Twice amended.) An anastomosis member to be arranged at an anastomosed site of first and second blood vessels to carry out the anastomosis of said first and said second blood vessels, said anastomosis member having a generally cylindrical body comprising at least one plate member to be brought into contact with both of said first and said second blood vessels, said plate member having integral therewith a plurality of protuberances formed on at least one of opposite surfaces thereof to be engaged with at least one of said first and said second blood vessels so as to prevent the dislocation of said first and said second blood vessels at said anastomosed site, each protuberance being formed from and extending from said body without leaving an aperture in said body.

15. (Twice amended.) An anastomosis method for the anastomosis of first and second blood vessels by the use of an anastomosis member to be arranged at an anastomosed site of said first and said second blood vessels, said anastomosis member having a generally cylindrical body comprising a pate member having integral therewith a plurality of protuberances formed on at least one of opposite surfaces thereof, said protuberances being formed from and extending from said body without leaving an aperture in said body, said method comprising the steps of:

inserting said anastomosis member into lumens of said first and said second blood vessels;

bringing said plate member into contact with at least one of said first and said second blood vessels; and

engaging said first and said second blood vessels with said protuberances so as to prevent the dislocation of said first and said second blood vessels at said anastomosed site.